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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,460	12/29/2005	Etienne Pouteau	112701-697	6141

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EXAMINER	
LAU, JONATHAN S	
ART UNIT	**PAPER NUMBER**
4173	

NOTIFICATION DATE	DELIVERY MODE
10/24/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

Office Action Summary	Application No.	Applicant(s)	
	10/562,460	POUTEAU ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2 pages/02 Mar 2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a national stage entry of PCT/EP04/07092, filed 30 Jun 2004; and claims benefit of foreign priority document EP 0301486.7, filed 30 Jun 2003.

Claims 1-6 are pending in the current application and examined on the merits herein.

Specification

The abstract of the disclosure is objected to because the sentence is missing a period at the end. Correction is required. See MPEP § 608.01(b).

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The disclosure is objected to because of the following informalities: No section headings appear in the specification of the instant application, making it unclear what text corresponds to what section.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating and/or improving insulin resistance or increasing insulin sensitivity or treating dyslipidemia, does not reasonably provide enablement for preventing insulin resistance or preventing dyslipidemia or for preparing a composition capable of performing these intended uses. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use or make the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a

disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: A composition for treating, preventing and/or improving insulin resistance, increasing insulin sensitivity or preventing dyslipidemia, and a for method treating, preventing and/or improving insulin resistance comprising administering said composition.

The state of the prior art: Prevent is defined as "keep from happening or arising; make impossible". See provided definition of prevent (definition of prevent, WordNet, cited in PTO-892). There is no prior art disclosing making insulin resistance or dyslipidemia impossible.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: The lack of any prior art disclosing making insulin resistance or dyslipidemia impossible means that one skilled in the art cannot predict the usefulness of a product or method to make insulin resistance or dyslipidemia impossible. Therefore the claimed invention is unpredictable.

The Breadth of the claims: The scope of the claims specifically includes prevention of insulin resistance and dyslipidemia.

The amount of direction or guidance presented: The specification speaks generally about the effect of treatment, such as decreased insulin sensitivity, and "that these effects tend to persist for some time after treatment has ceased." See instant specification, page 11, lines 17-20.

The presence or absence of working examples: The only working examples provided are directed towards treating and/or improving insulin resistance or increasing insulin sensitivity. For example, see instant specification, examples 1 and 2 spanning pages 9 through 11.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as prevention of insulin resistance and dyslipidemia. See MPEP 2164.

The quantity of experimentation necessary: In order to practice the invention with the full range of all possible treatment methods beyond those known in the art, (such as treating and/or improving insulin resistance) one skilled in the art would undertake a novel and extensive research program to show that the treatment method made insulin resistance or dyslipidemia impossible. Because this research would have to be exhaustive, and because it would involve such a wide and unpredictable scope of treatment methods, it would constitute an undue and unpredictable experimental burden.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the breadth of the claims, Applicants fail to provide information sufficient to practice the claimed invention for prevention of insulin resistance and dyslipidemia.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4 provide for the use of a composition for the preparation of a nutritional and/or pharmaceutical composition, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Lapré et al. (US Patent 5,972,399, issued 26 Oct 1999, cited in PTO-892).

Lapré et al. discloses a food with a coating that comprises a polysaccharide that reduces the core's glycemic response (column 6, lines 45-47), wherein the polysaccharide is preferably pectin (column 7, line 65-66), addressing instant claims 1 and 2. Lapré et al. discloses administering the food is useful for treating individuals suffering from diabetes and hypoglycemia (column 7, lines 10-11), addressing instant claim 5. Lapré et al. discloses the food is preferably 0.1-5% by weight pectin (column 9, lines 41-44), addressing instant claim 3. Lapré et al. discloses that the method of treating diabetes is the method of treating insulin resistance (column 4, lines 1-5), whereas the method of treating hypoglycemia is a method of treating sensitivity to excessive circulating insulin (column 4, lines 12-14), addressing instant claim 4.

Claims 1, 2 and 4-6 rejected under 35 U.S.C. 102(b) as being anticipated by Eliaz (US Patent 6,462,029, issued 08 Oct 2002, cited in PTO-892).

Eliaz discloses a modified pectin used alone or in combination (spanning column 3, line 67 and column 4, line 1) in a pharmaceutical composition (column 3, lines 53-54), addressing instant claim 1. Eliaz discloses the use of the low molecular weight pectin of modified citrus pectin (column 1, line 42), addressing instant claim 2. Eliaz discloses the use of the pectin composition in the removal of cholesterol (column 1, line 23), as well as the effect on glucose tolerance and glucose absorption in the treatment of diabetes, a method of treating insulin resistance by treating the disease of diabetes (column 2, lines 52-57), addressing instant claims 4 and 5. Eliaz discloses a dosage level of 5-1500 mg per kg body weight (column 3, lines 55-59), anticipating the ranges in instant claim 6.

Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Wolt et al. (US Patent 6,706,305, filed 31 Oct 2001, cited in PTO-892). Applicant should also be made aware of the Pre-Grant Publication US 2003/0082287 of Wolt et al. published on 01 May 2003.

Wolt et al. discloses a nutritional and/or pharmaceutical composition, low glycerin index baked bread, (abstract, line 1) used to treat insulin resistance (column 1, lines 5-9) prepared with the soluble fiber of gums, apple pectin or citrus pectin (column 3, lines 42-44), addressing instant claims 1 and 2. Wolt et al. discloses the soluble fiber content

is at least 0.8 % wt or about 1.0 % wt to 1.6 % wt of the composition (column 2, lines 28-31), addressing instant claim 3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eliaz (US Patent 6,462,029, issued 08 Oct 2002, cited in PTO-892).

As recited above, Eliaz discloses a modified pectin used alone or in combination (spanning column 3, line 67 and column 4, line 1) in a pharmaceutical composition (column 3, lines 53-54), addressing instant claim 1. Eliaz discloses the use of the

modified pectin administered with excipient, specifically in the form of a gelatin capsule (column 5, lines 33-34 and 36-38).

Eliaz does not specifically disclose a composition wherein the amount of acetogenic fiber is in the range of from 0.2 to 90% by weight of the composition.

It would have been obvious to one of ordinary skill in the art at the time of the invention to formulate the modified pectin composition of Eliaz wherein the excipient and gelatin capsule is at least 10% by weight of the composition. It is well-known practice in formulation of pharmaceuticals such as gelatin capsule to optimize the amount of excipient in a pharmaceutical with a reasonable expectation of success. Therefore a gelatin capsule wherein the amount of modified pectin is in the range of from 0.2 to 90% by weight of the pharmaceutical composition as a result of routine optimization would have been obvious to one of ordinary skill in the art at the time of the invention.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Ardin Marschel can be reached on 571-272-0718 or Cecilia Tsang can be

reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSL

Ardin H. Marschel 10/20/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER